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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/652,842

08/29/2003

Bret A. Ferree

BAF-16402/29

2836

7590

07/14/2004

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EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/652,842

Applicant(s)

FERREE, BRET A.

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/17/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, 10-11, 14-15, and 20-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. 6,595,998. Johnson et al. discloses the invention as claimed comprising: A method of fixing an artificial disc replacement to a vertebral endplate by locating a component of the ADR in spaced-apart relation to the vertebral endplate; and introducing cement between the component and the vertebral endplate; wherein the ADR component is a rigid endplate (it is inherent that material listed would produce a rigid endplate; col. 9, line 40 "dense"); made of polyethylene or other suitable polymeric material (see col. 9, lines 29-51 for materials); (col. 5, lines 38-41, col. 6, lines 49-51, col. 9, lines 61-63); wherein the cement can contain an antibiotic (col. 9, line 57); forming a receiving hole or cavity in the vertebral body; wherein the ADR comprises a rim (266) wherein cement is injected under fluoroscopic observation (col. 22, line 49).

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The steps of forming a passage through the vertebra having the endplate to inject the cement are inherent.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Gould et al. 2004/0067876. Johnson et al. has been disclosed above however they do not mention a hypotensive anesthesia prior to fixing the ADR. Gould et al. teaches the use of hypotensive anesthesia.[0009]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize this type of anesthesia prior to fixing an ADR because it would help control any patient that may suffer large amounts of blood loss.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Trieu 2004/0133280. Johnson et al. has been disclosed above however Johnson et al. does not specify the use of a hemostatic agent prior to fixing the ADR. Trieu teaches ADR replacements that utilize cement and Hemostatic agents [0085]. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to take the invention of Johnson et al. and utilize haemostatic agents in order to arrest any hemorrhaging that may occur.

7. Claims 12, 17-19 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Carbone 5,340,362. Johnson et al. has been disclosed above however and while Johnson et al. does mention that the introduction of cement between the component and the vertebral endplate utilize a separate tool that is removed before the endplate is placed in a spaced-apart relation to the vertebral endplate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize separate tools for different stages of filling the cavity and ADR with cement because a tool for inserting cement may be *structurally* different (i.e. a cannula nozzle) than the tool for inserting an ADR (i.e. a tool with mating structure of the ADR).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mathews 2004/0106999 and Weikel et al. 2002/0177866 show related material.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

10. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J. Jackson', with a long, sweeping horizontal line extending to the right.

Suzette J. Jackson
09 July 2009